



Communication / Advance Warnings

- Distributor Initiative
- Reminder letters sent to industry
- Host industry conferences
- Speak at various conferences
- Meetings with HDMA and industry reps
- Educate downstream registrants to do their part
- Congressional testimony



ARCOS data

- Importance of knowing your own data
- Early warning sign for an emerging trend?



Sharing Suspicious Registrant Info


- May involve ongoing criminal investigation
- Info may be protected under Grand Jury rules
- Requirement to identify and report suspicious orders does not always involve diversion
 - In many instances the registrant knew or should have known what was happening by way of their own data
- Previous litigation for doing so

Approving SOM Systems

- One-size-fits-all doesn't work
- Allowing for differences in business models
- Allowing for innovation and flexibility
- Prevent a false sense of security
- Doing so might create complacency
- Responsibility of each registrant



What is the Agency Looking to Accomplish?



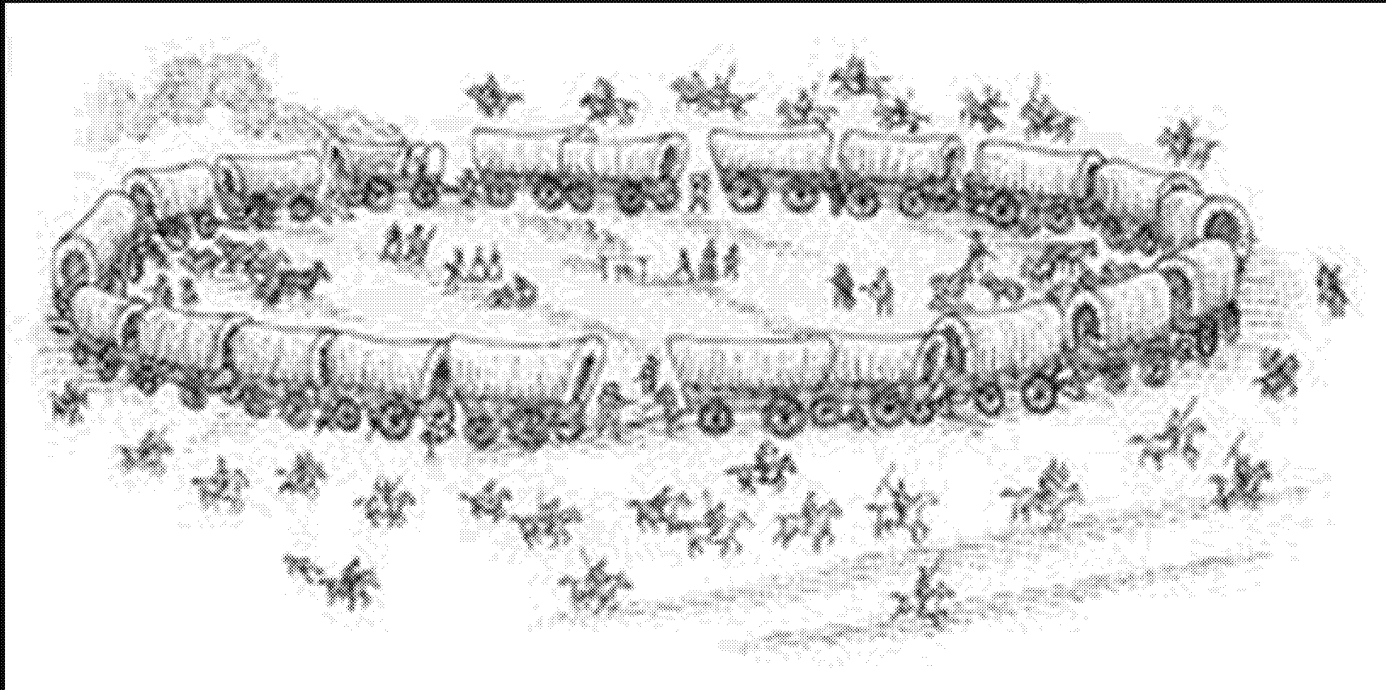
Protect the Public Health and Safety – Stop the Hemorrhaging

Distinction Between Products

- Handling controls versus non-controls



Maintain the Closed System of Distribution – United Front





Fixing A National Problem

The 3 Ps

- Position
- Perseverance
- Power

Distributors Have Great Power

- Individually and collectively
 - Your DEA registration
 - Ensure timely distribution to prevent an uninterrupted supply; and
 - You control the supply to downstream customers



**“With Great Power Comes Great
Responsibility”** *Voltaire 18th Century*



“Know Your Customer”

- Legal obligation?
- To what extent?
- Good business practice
 - Leveraging your sales personnel
- Internal vs external information



Detecting Suspicious Orders

- Use of Robust Systems
 - Must remain vigilant / keep abreast of evolving or emerging trends.
 - Identify “red flags” associated with evolving or emerging trends quickly
 - Adaptability of your SOM program to evolving or emerging trends

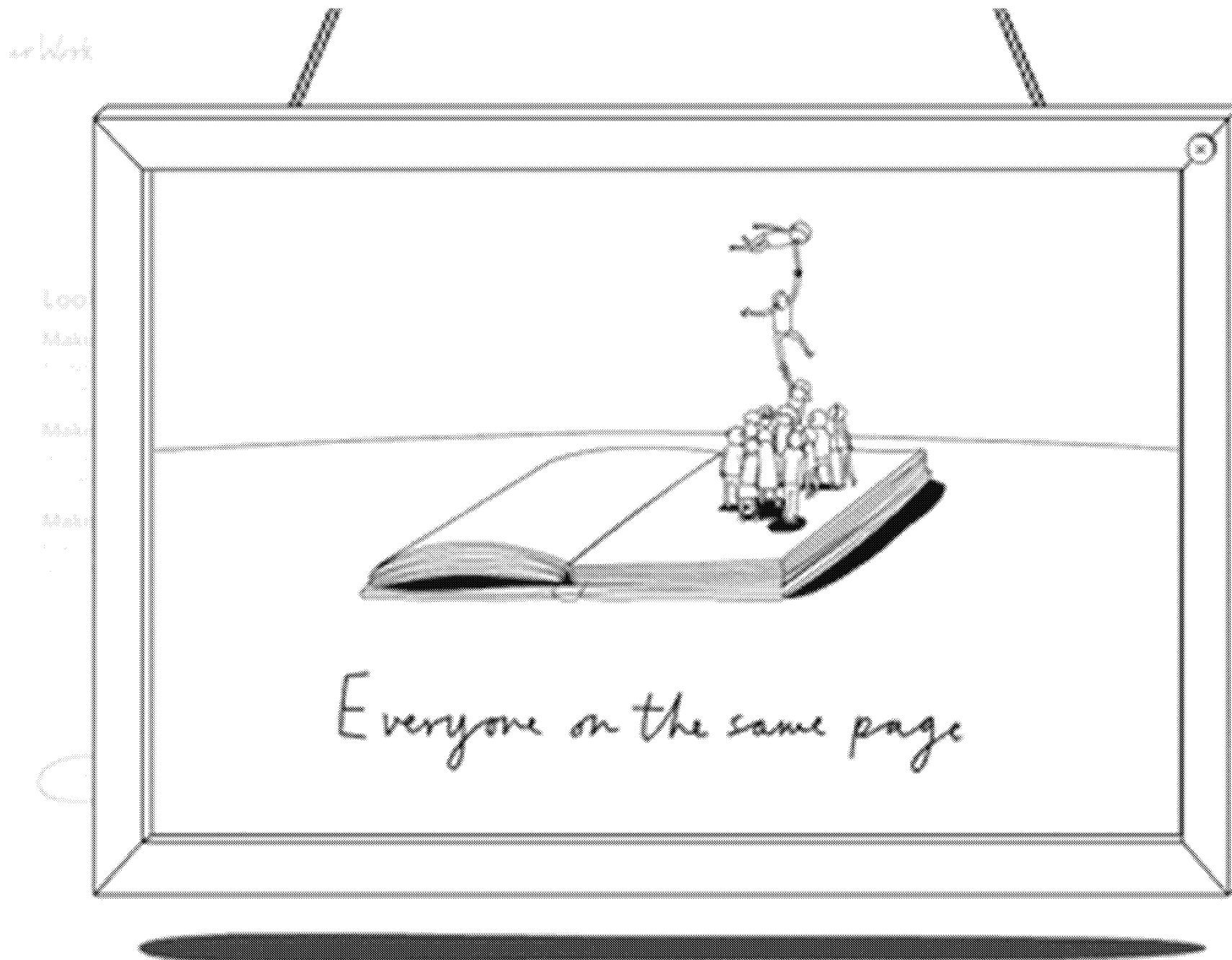


Detecting Suspicious Orders

- Do not rely solely on thresholds or algorithms as a shortcut to detecting suspicious orders
- Most importantly, USE your system
 - Cannot ignore warning signs
 - Listen to employees when they do identify suspicious orders.

Employees

- What is their background or experience?
- Proper Training
 - Initial
 - Updated
 - Training the right personnel
 - Company's Leadership and Field Managers
 - Sales reps
 - Regulatory/compliance personnel





Keeping Your Eye on the Ball

- Market dynamics can affect due diligence efforts.
(shifting to different drugs based upon availability, new drugs or tamper-resistant formulations)
- Newly enacted laws can create shifts in diversion methods
- Cannot always rely on what your customers say to dispel a suspicious order. *“Trust, but verify”*



What Impacts Diversion?

- New technology – the Internet
 - Rogue Internet pharmacies
 - Dissemination of information, both good and bad, at lightning speed



What Else Impacts Diversion?

- Compliance!!!!!!!
 - The checks and balances created by the Controlled Substances Act work
 - Registrants are a force-multiplier
 - Without sustained sources of supply major diversion schemes wither away



Newton's Law of Physics

Need for Vigilance

- Increase in DEA enforcement actions
- Changes in Florida law
- Pain clinic issue became a retail pharmacy issue
 - Pharmacies affiliated with the clinic or
 - To any retail pharmacy with oxycodone in supply
 - Further shift to nationwide mail order pharmacies
- Disruption of oxycodone supply
 - Abuse of hydromorphone increased

Speaker Notes for Slide 47

Bullet 1: Operations: Pill Street Blues; Pill Nation I and II; Juice Doctor
Increased enforcement action against wholesalers/distributors; impact on supply



Positive Trends?

SAMHSA NSDUH data: The number of persons 12 years and older abusing pain relievers:

- 2012 – 4.9 million
- 2011 – 4.5 million
- 2010 – 5.1 million
- 2009 – 5.3 million
- 2004 – 4.3 million



Positive Trends con't

Florida Medical Examiner's Office data:

➤ Oxycodone related deaths

- 2012 – 735
- 2011 – 1,247
- 2010 – 1,516

➤ Benzodiazepines

- 2012 – 1,337
- 2011 – 1,950
- 2010 – 1,726

Florida Department of Law Enforcement, “*Drugs Identified in Deceased Persons by Florida Medical Examiners 2012 Report*”, September 2013



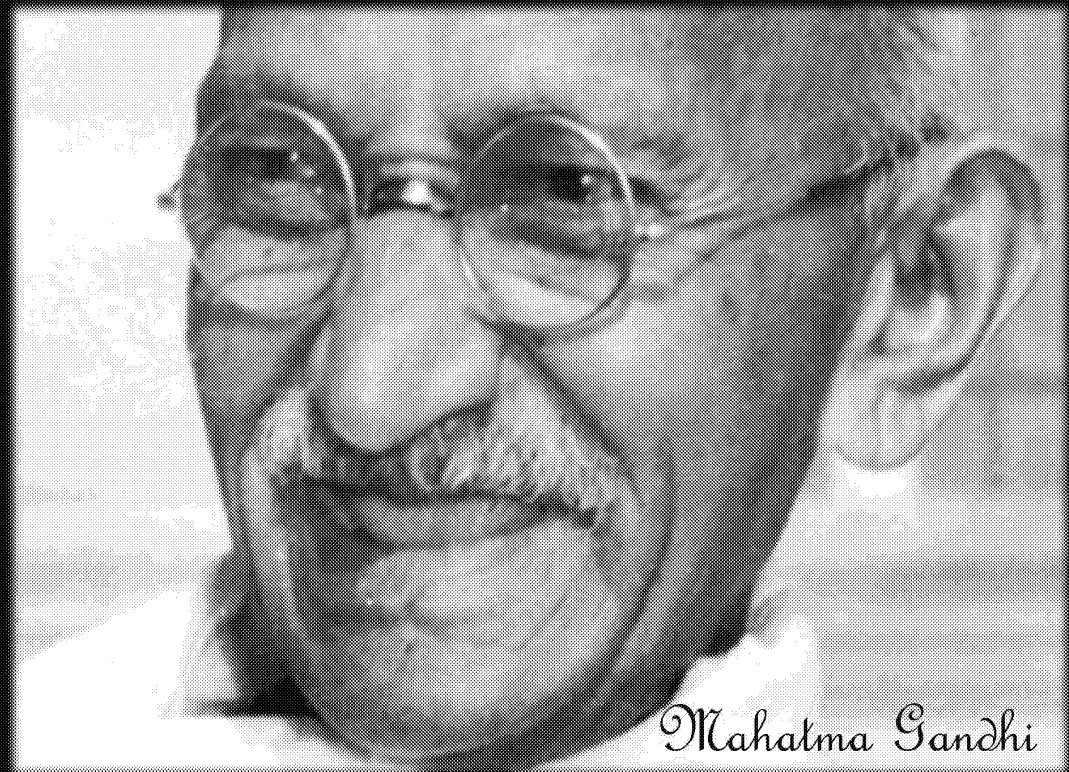
Working in Today's Environment

- Recognizing where we are relative to prescription drug diversion and abuse
- Understanding who can make the greatest impact
- Level playing field across the industry



The irony of prescription drugs

**“The future
depends on
what you do
today”**



Mahatma Gandhi



Thank You!

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